REMARKS/ARGUMENT

Applicant expressly thanks the Examiner for his cooperation with Applicant's attorney and in reviewing the issues remaining with the application and arranging for an interview to be conducted with both he and Examiner Warden on June 22, 2004.

Claims 1-90 are pending in the application. Claims 1-16, 42-44, 48, 51, 52, 55-69, 71, 72 and 73-90 have been withdrawn from consideration. Claims 17-41, 45-47, 49, 50, 53, 54 and 70 have been examined but are now rejected either under 35 U.S.C. §102 or 35 U.S.C. §103 in view of the patent issued to Welle either alone or in view of the patent issued to Brand et al. Claim 84 has been amended to depend from Claim 17. Thus, Claims 84, 85 and 90 now are grouped with Claims 17-41, 45-47, 49, 50, 53, 54, and 70. Consideration of Claims 84, 85 and 90 in view of the patent issued to Welle and/or Brand et al is respectfully requested. The issues remaining include:

1. Whether the requirement for restriction is proper and how many additional applications need to be filed to fully cover Applicant's inventions as claimed in Claims 1-90. Applicant submits that it is improper, but that no more than two divisional applications should suffice.

The original requirement for restriction separated Applicant's identification (for example Claims 1-16) from Applicant's method of objectively identifying batched products (Claims 17-41) and grouped with the identification claims (Claims 1-16) Claims 43, 44, 51, 52, 55-69, 71, 72. This restriction divides Applicant's method from Applicant's identification. However, the most recent restriction also grouped Applicant's method Claims 73-90 with Applicant's identification claims. The Examiner stated:

> "Claim 73 linking the unknown concentrations to a known concentration for analyzing stable naturally occurring isotopes.

> The original claims are directed to just analyzing isotopes and arranging into a mathematical array in a readable form and not linking an unknown isotope to a known isotope. Thus newly submitted claims 73-90 are directed to an invention that is independent or distinct from the invention originally claimed."

The Examiner has thus concluded that newly submitted Claims 73-90 are directed to an invention that is independent or distinct from the invention originally claimed. However, Claim 70 and Claims 73-90 appear to Applicant to be directed to the same invention as Claims 17-41, 45-47, 49, 50, 53, 54 and 70. While the broader claims, e.g. Claim 17, include the steps of analyzing a batched product, formulating said mathematical array, assembling product information, indexing product information, and maintaining said index, the first dependent claim (Claim 18) adds the steps of measuring the concentration of one or more isotopes in a comparable substance and comparing the concentrations of said one or more isotopes of said comparable substance with a concentrations of said mathematical array to identify the substance. This comparing step includes the same procedure of linking an unknown isotope to a known isotope as claimed in Claims 73, 74 and its dependent Claims 75-90. Thus, presently Applicant does not see why Claims 73-90 are grouped with Applicant's identification claims (Claims 1-16, 42-44, 48, 51, 52, 55-69, 71 and 72) nor does Applicant fully understand as to whether, if Applicant files an application on all of the withdrawn claims, there will be another restriction between Claims 73-90 and Applicant's identification claims.

Applicant conversed with the Examiner on Wednesday, May 26, 2004, regarding the upcoming interview and the requirement for restriction. Applicant understood from the Examiner that the restriction between Claims 1-16, 42-44, 51, 52, 55-69 and 71 and 72 and Claims 17-41, 45-47, 49, 50, 53, 54 and 70 remain. The Examiner opined that if a divisional was filed containing Claims 1-16, 42-44, 51-52, 55-69, 71 and 72 that Claims 74-90 would be

divided therefrom and possibly Claim 73 would be divided into a third group of claims. Based upon this information Applicant has filed one divisional application including 1-16, 42-44, 51, 52, 55-69, 71 and 72 and will file a second divisional application including Claims 74-90. Applicant reserves the right to amend Claims 73, 74-90, and 48 to include those claims with Claims 17-41, 45-47, 49, 50, 53, 54 and 70.

2. Whether the ambiguity of the language "a plurality of naturally occurring stable isotopes of a composition" (batched product) is cured by the substitution of the language "a plurality of naturally stable isotopes of a composition in their unaltered concentrations." Applicant submits yes.

Presently, the Examiner is reading this language on the Welle reference and its disclosed compositions in which non-naturally occurring isotopes (in the composition) are artificially added or, "salted" into known compositions. The Examiner acknowledges that Welle discloses a "tagging method" but goes on to identify Welle with tagging with naturally occurring stable isotopes such as Europium and Neodymium. While each of the claims now requires "naturally occurring stable isotopes of said composition" which would exclude those used for tagging by Welle, Applicant believes that this issue can be laid to rest by amending each of the claims to include "naturally occurring stable isotopes in their unaltered concentrations."

3. Whether the amendment to each of the claims to include the language "stable naturally occurring isotopes in their unaltered concentrations" eliminates the anticipation rejections under 35 U.S.C. §102 because an additional reference combined with Welle would need to be utilized to teach or suggest each and every one of the elements of Applicant's claims including the language "stable naturally occurring isotopes in their unaltered concentrations." Applicant submits yes.

Anticipation rejections under 35 U.S.C. §102 must be based on a single reference. Reconsideration of Claims 17-22, 25-33, 41, 45-54 and 70, rejected under 35 U.S.C. §102(b) as being anticipated by Welle is respectfully requested. Claim 48 previously depended from Claim 5 and has been amended to depend from Claim 45. Thus, Claim 48 has been included in this rejection by Applicant. Claim 84, previously depending from Claim 74, has been amended herein to depend from Claim 17. Thus, Claims 84, 85, and 90 have been included in this rejection by Applicant.

Each of these claims have been amended to require the analyses before made on unaltered stable isotopes of the composition to be identified to be made at their naturally occurring or unaltered concentrations. These amendments to these claims clarify any existing ambiguity of these claims as to whether or not they relate to a "tagging" method in which a taggant not naturally occurring in the composition is added to the composition and the analysis made of the taggant or whether the analysis is made of naturally occurring stable isotopes without anything being added to the composition. The Examiner acknowledges that Welle teaches an isotopic tagging method and that Applicant's claims are directed to what has been identified as a "finger printing method" or "natural tracer method" in which stable naturally occurring isotopes of the composition are analyzed in their naturally occurring or unaltered concentrations. By these amendments Applicant respectfully submits that the rejection has been overcome for two reasons. First, the patent issued to Welle does not teach or suggest each and every element of the claims. Second, to be anticipated under 35 U.S.C. §102, each and every element of the claims must be found in a single reference i.e. Welle, whereas these claims now include several elements which cannot be found in Welle thus if rejected at all require an

additional reference other than Welle or another reference in addition to Welle which is not permitted under 35 U.S.C. §102.

Presently, scientists who work on "natural tracers" and those who work on "taggants" work in different professional worlds. Prior to 1999, there were few if any "natural tracer" scientists who worked on industrial problems as described here because there was no generally agreed upon definition of precision to define the process and a generalized uneasiness in the minds of analytical chemists regarding isotopic mass balances and fractionations. See "An Introduction to Isotopic Calculations," Hayes, J.M., 1/4/2004. Applicant served to define the situation with respect to precision in three steps since 1999: (i) shortly after the filing of this application on August 17, 1999, Applicant first made a presentation at the Sixth Canadian Continuous Flow-Isotope Ratio Mass Spectrometry (CF-IRMS) Meeting held in Victoria, British Columbia (August 15-18, 1999) on the topic of a generally applicable definition of precision for isotopic measurements; (ii) On July 5, 2001, Applicant had accepted for publication the key points of that CF-IRMS presentation on precision in a paper entitled, "Quantitative Estimates of Precision for Molecular Isotopic Measurements" in the journal Rapid Communications in Mass Spectrometry (2001; Vol. 15:1554-1557); and (iii) Applicant published a paper "A Practical Definition of Precision for Stable-Isotopic Measurements: Significance for Multi-Stable Isotopic Analysis" on April 17, 2004 detailing the development of the ideas of a practical definition of stable-isotopic precision.

The definition of precision described in the Rapid Communications in Mass Spectrometry paper has since been accepted by the "natural tracer" scientists. See appendix 2 and 3. Prior to Applicant's presentation at that CF-IRMS meeting, a lively discussion in an open session occurred between 60-90 analytical chemists from all over the world who shared their

experimental results about naturally occurring stable isotopes to identify unknown compositions of natural materials and their varied and undefinitive ideas about precision. The consensus was that there was no agreed upon definition of precision that would allow naturally occurring stable isotopes to be utilized in the manner now proposed by Applicant in this application. Leading colleagues, including the director of the CF-IRMS meeting, encouraged the Applicant to commit his ideas to a scientific paper and he did so. Applicant began his summary paper discussing the historical background:

> "Professors of college-level statistics often tell their students that "Means [i.e., averages] are meaningless without standard deviations." At the August 15-18, 1999 international meeting on continuous flow isotope-ratio monitoring mass spectrometry (Sixth Canadian CF-IRMS Meeting; Victoria, British Columbia), it was generally recognized in an open-floor discussion of ~60-90 mass spectrometrists that the lack of a practically-useful definition of precision hindered most practitioners from meaningfully comparing isotopic data on an equal basis. The discussion wallowed in a variety of *ad hoc* approaches, none of which was recognized as generally satisfactory.

Applicant took this initiative to advance this area and to rigorously define precision in a scientific paper that would make stable-isotopic identification of batched materials a scientifically sound and an industrially useful and precise method in the Rapid Communications in Mass Spectrometry paper.

4. Whether Applicant's claims are rendered obvious under 35 U.S.C. §103 in view of the prior art which includes the patent issued to Welle, or more specifically? Applicant submits no.

A. Whether prior to 1999 anyone taught or suggested using stable naturally occurring isotopes in their unaltered concentrations to identify unknown compositions. Prior to 1999, Applicant submits that although "taggant methods" and "finger printing

methods" or "natural tracer methods" were generally acknowledged in a qualitative sense, the key element of precision (which led to useful estimates of dynamic range and specificity) were not usefully defined and therefore prohibited their use in industrial applications which require a generally accepted and practical definition. "Finger printing" and "natural tracer" methods were discussed, but not utilized.

B. Whether Applicant's definition of "precision" disclosed in his patent application filed in July 1999 renders all claims unobvious and patentable. Prior to 1999 stable naturally occurring isotopes were not being used for identification of unknown compounds for the following reasons:

1. The analyses are very expensive compared to many other analytical measurements used in product security,

2. Virtually all attempts to identify unknown compositions usually utilize less than 10 isotope analyses because of time and cost limitations,

3. It was known in the literature that isotopic mass balances were impossible in "open" or "non-conservative" reactions, and

4. It was also well known that averages of such analyses were without a meaningful standard deviation (i.e., an estimate of precision) and generally worthless. By definition, without a standard deviation there can be no dynamic range, without a dynamic range there can be no specificity.

Applicant's definition of precision now allows the scientific, precise identification of unknown compounds utilizing stable naturally occurring or unaltered isotopes in their naturally occurring concentrations.

C. Whether the usable "finger printing" and "natural tracer" methods and "identification" using "natural tracers" first proposed by Applicant in his patent application utilizing "pooled standard deviations" were obvious under 35 U.S.C. §103. While pooled standard deviations were known among statisticians prior to 1999, to our knowledge, no one applied them to stable-isotopic analyses and specifically nobody applied them to identifying unknown compositions by analyses of naturally occurring stable isotopes in their naturally occurring concentrations as witnessed at the 1999 CF-IRMS meeting discussion mentioned above and the Applicant's resulting paper on precision. Mathematicians apparently did not know of the need; analytical and isotope chemists if all knowledgeable would be wary of the lack of mass balances around "open" or "non-conservative" reactions and generally did not know how to apply the mathematics; and neither knew how to apply "pooled standard deviations" to analyses of a plurality of naturally occurring stable isotopes of an unknown product in their naturally occurring concentrations for the purpose of identifying unknown products.

D. Was Applicant's provision of a usable identification comprising a mathematical array of analytical results and a method of objectively identifying batched products obvious to those persons skilled in the art having knowledge of both analytical chemistry and the mathematics of statistics? Clearly, no.

Those skilled in the art having knowledge of both statistics and isotope chemistry would have included persons such as Welle and other "taggant chemists." None of them proposed Applicant's claimed inventions, particularly, the use of naturally occurring stable isotopes in their naturally occurring or unaltered or ambient concentrations as a basis for a method of product security. The most well read chemists generally were wary

of "natural tracer" chemists because of the lack of isotopic mass balances in "open" or "non-conservative" reactions. Evidencing the unobviousness of Applicant's provision of a usable identification and method of objectively identifying batched products utilizing analyses of a plurality of naturally occurring stable isotopes in their naturally occurring or unaltered concentrations is the separation of "taggant" chemists and "natural tracer" chemists into wholly different fields of science today. "Natural tracer" scientists are typically earth scientists and observationalists who typically work on naturally-existing materials. "Taggant" chemists are typically experimentalists who perform controlled artificial experiments in laboratories. They generally attend separate scientific meetings and publish in different journals. There are thousands of biomedical/technology scientists who will use only "taggants" in their work, but never "natural tracers" in their careers. Generally, there are thousands of pharmaceutical/technology scientists who will never use "natural tracers" in their careers. "Taggant" chemists solved the lack of precision by purposefully altering the composition of one or more of the isotopes to be measured. "Natural tracer" chemists solved the potential lack of precision by utilizing Applicant's pooled standard deviations.

Reconsideration of Claims 23, 24 and 34-40 rejected under 35 U.S.C. § 103 as being unpatentable over Welle in view of Brand et al and consideration of Claims 17-22, 25-33, 41, 45-50, 53, 54, 70, 84, 85, and 90 under 35 U.S.C. §103 in view of Welle or in view of Welle and Brand et al is respectfully requested. Consideration of Claims 1-16, 42-44, 51, 52, 55-69, 71 and 72, and Claims 74-90 of Applicant's divisional applications is also respectfully requested.

In August of 1999 at the Sixth Canadian CF-IRMS Meeting in Victoria, British Columbia in an open floor discussion of approximately 60-90 mass spectrometrists, the general consensus was that the lack of a practically useful definition of precision hindered most practitioners from meaningfully comparing isotopic data at naturally occurring concentrations. Right after that time no one known to Applicant was utilizing analyses of naturally occurring stable isotopes in their naturally occurring concentrations to rigorously define identify unknowns for purposes of product identification.

Subsequent to this meeting, Professor Robert Dias of Old Dominion University in Virginia wrote Applicant stating:

> "John, I use your 2001 RCMS publication 'Quantitative Estimates of Precision for Molecular Isotope Measurements' on a regular basis in my graduate course in stable isotope chemistry. I seem to recall a Canadian user's meeting [1999] where the topic turned to our [fields] rather inconsistent and (at times) sloppy ways of reporting our 'errors' in isotopic measurements. We after all, really report the precision of our replicate analyses. Your paper makes the point that 'error' and the replicate standard deviations that we report as 'error' are two very different things, and that we are getting very lax and crossing over incorrect practices.
>
> I have copied your recent JPBA paper on pharmaceuticals and will no doubt be using it in my class this fall."

Applicant's work on utilizing pooled standard deviations in order to provide a practically useful definition of precision as first stated in his published paper entitled "A Practical Definition of Precision for Stable-Isotopic Measurements: Significance for Multi-Stable Isotopic Analysis" was in fact unobvious. While analyses of naturally occurring concentrations of naturally occurring stable isotopes had been preformed before and pooled standard deviations had been known by statistical mathematicians before, no one prior to Applicant's definition of precision put them together to make useful the use of a plurality of analyses of naturally occurring stable

isotopes in their natural concentrations to identify unknowns. The long felt unmet need for such a practically useful definition of precision is additional evidence of invention.

The claims of this application however go far beyond the mere provision of a practically useful definition of precision for a plurality of analyses of stable isotopic concentrations in their naturally occurring concentrations. Once precision was defined, there remained the question of how such techniques could be utilized to identify unknown compositions, how such techniques could be utilized to take one unknown and identify it amongst the typically millions-to-billions or more of possible stable isotopic compositions in a manner adaptable to commercial laboratories, how one could use these techniques in a way such that the precision could be applied or in other words, the appropriate error could be predetermined, and how all of this could be done in a present day laboratory setting in which thousands of analytical determinations could be made on a daily basis. Applicant answered all of these questions by providing an identification of each unknown in the form of a mathematical array of concentrations of isotopes or other words arranging the results of analysis of natural occurring stable isotopes of the unknown in their naturally occurring concentrations in a mathematical array and formulating the mathematical array so as to be in a readable and comparable form.

Applicant's mathematical array cannot be compared with the tables of Welle. Tables by definition are rows and columns of numbers arranged to convey information in comparison. Tables normally have headings and identification of the type of information to be found in each of the rows and the columns, and information distinguishing each row from the other rows and information distinguishing each column from the other columns. Further, since tables are to convey information, the information found in various rows and columns are usually in a series of descending or ascending order. Applicant's mathematical array does not convey information and

is not systematic or ordered, but instead captures the random and quantitative character of isotopic analyses. It is an identification of an unknown batched product which when compared with other similarly constructed mathematical arrays, allows that unknown batched product to be identified. The results of analysis may be listed in rows and columns or for that matter in other geometrical shapes such as concentric circles or spirals or any other configurations and the data is not ordered in any way to convey information as is the data in tabular form. Data in a mathematical array only needs to be in the proper position in the array. There needs to be no relationship between data in one position and data in another position. Thus the data may be positioned in the mathematical array in a totally random manner to enhance security. Applicant's mathematical array is readable and comparable in the same fashion as any list of numbers in whatever geometric form. The mathematical array is readable by human sight, electronically as with known computerized software, or bar code technology.

Also known were computer techniques by which groups of letters or integers could be searched for in a data base and matched up with identical groups of letters or integers. One example would be searching for a name in a database including all of the telephone directories of the United States. While all groups of letters and integers could be searched for in a database, no one prior to Applicant knew how to convert the empirical data of a plurality of analyses of naturally occurring stable isotopes in their natural concentrations to utilize these techniques. Additionally, no one knew how to place the empirical information into a form that allowed one to determine in advance the error of the comparison or identification statistically. Applicant solved both dilemmas by providing Applicant's identification and methods disclosed and claimed in Applicant's application.

Applicant's methods are of two forms. The first includes Claims 17 and 20-41, 45, 46, 50, 53, 54, 70, 84, 85, and 90. The second includes those claims wherein a comparison of mathematical arrays is utilized to identify an unknown product such as Claims 18, 73, 74-83, and 86-89.

Neither the patent issued to Welle nor the patent issued to Brand et al teaches or suggests Applicant's method as claimed in Claims 17, 45, 50, and 70 whether taken alone or in combination with each other.

> "Claim 17. The method of objectively identifying batched products comprising the steps of analyzing a batched product for the concentration of a plurality of the naturally occurring stable isotopes of said product in their unaltered concentrations, arranging said concentrations of said isotopes into a mathematical array, formulating said mathematical array into a readable form, assembling product information, indexing said product information and said readable form thereby forming an index, and maintaining said index and said product information."
>
> "Claim 45. A method of providing an objective identification of a batched product comprising the steps of analyzing a plurality of naturally occurring stable isotopes of said batched product in their unaltered concentrations, deriving empirical information from said analyzing step, and arranging said empirical information into a numerical array."
>
> "Claim 50. A method for identifying a composition comprising identifying a plurality of the naturally occurring stable isotopes of said composition in their unaltered concentrations, analyzing said composition for the concentrations of a plurality of naturally occurring stable isotopes of said composition, deriving empirical information from said analyzing step, arranging said empirical information into a numerical array and formulating said numerical array into a readable form."
>
> "Claim 70. A method of providing an objective identification of a batched product comprising the steps of analyzing a batched product for the naturally occurring concentrations of a plurality of the naturally occurring stable isotopes of said batched product, arranging said concentrations of said isotopes into a mathematical array, formulating said mathematical array into a readable form,

> assembling product information with regard to said batched product, indexing said product information and said readable form to a description of said product thereby forming an index, and maintaining said index and said product information and said readable form."

Neither patent teaches or suggests "analyzing a plurality of naturally occurring stable isotopes of said batched product in their unaltered concentrations" nor arranging the results of the analyses "into a mathematical array" nor "formulating said mathematical array into a readable form."

Neither the patent issued to Welle nor the patent issued to Brand et al teach or even suggest Applicant's method of comparing or linking unknown compositions to known compositions by Applicant's method as claimed in Claims 73 and 74 whether taken alone or in combination with each other.

> "Claim 73. A method of linking an unknown composition to known compositions comprising the steps of analyzing a plurality of stable naturally occurring isotopes of a plurality of known compositions in their unaltered concentrations, deriving empirical information from said analyzing step of said known compositions, arranging said empirical information from said known compositions into numerical arrays, placing said numerical arrays and product of said known compositions into an index, analyzing a plurality of stable naturally occurring isotopes of an unknown composition, deriving empirical information from said analyzing step performed on said unknown composition, arranging said empirical information from said unknown composition into a numerical array, comparing said numerical array of said unknown composition to said numerical arrays of said index, determining whether said numerical array of said unknown composition matches any of the numerical arrays of said index.
>
> Claim 74. A method of comparing batched products comprising the steps of analyzing a first plurality of stable naturally occurring isotopes of a second plurality of elements of a third plurality of batched products in their unaltered concentrations thereby generating a fourth plurality of isotopic data, said fourth plurality of isotopic data being for each of said third plurality of batched products, respectively, listing said fourth plurality of isotopic data, listing identifications of said third plurality of batched products from which each of said fourth plurality of

> isotopic data were derived, linking said identifications with said isotopic data thereby forming an index, analyzing a fifth plurality of stable naturally occurring isotopes of a sixth plurality of elements of an unknown batched product thereby generating a seventh plurality of isotopic data, comparing said seventh plurality of isotopic data with said fourth plurality of isotopic data to identify said unknown product as one of said third plurality of batched products or to distinguish said unknown product from said third plurality of batched products, said fifth, sixth, and seventh plurality being less or equal in number to said first, second, fourth plurality, respectively, and determining the precision of said comparing step by selecting said fifth plurality of stable naturally occurring isotopes of said unknown product."

The patents issued to Welle and Brand et al whether taken alone or in combination with each other do not teach "analyzing a plurality of stable naturally occurring isotopes of a plurality of known compositions in their natural concentrations, deriving empirical information from said analyzing steps of said known compositions and arranging said empirical information from said known compositions into said numerical arrays" or "formulating an index with said numerical arrays and said product of said known compositions" and "analyzing stable naturally occurring isotopes of an unknown composition in their naturally occurring concentrations, deriving empirical information from said analyzing step performed on said unknown composition, arranging said empirical information from said unknown composition into a numerical array" or "comparing said numerical array of said unknown composition to said numerical array of said unknown composition to said numerical array of said index, determining whether said numerical array of said unknown composition matches any of the numerical arrays of said index" to identify said unknown composition as required in Claim 73 and otherwise claimed in Claim 18 and 74-90.

In contrast, the patent issued to Welle discloses a method for identifying materials using an isotopic taggant composition and a taggant composition for retrospective identification of

materials using artificially controlled abundance ratios of multiple isotopes in each of one or more elements of the taggant composition. The taggant composition is proposed to comprise multiple artificial taggant elements, with each of the taggant elements containing two or more stable isotopes presented in a selected artificial abundance ratio corresponding to an identification code. Nothing could be further from the method of Applicant.

Of all of the known elements known to man, many of these elements can be found in nature in the form of multiple isotopes. Of all of the isotopes known, there are two clearly defined groups of isotopes. The first of these groups of isotopes are known as radioactive or unstable isotopes inasmuch as they have finite half-lives and degenerate over time. The other well defined group of isotopes is stable isotopes, or non-radioactive isotopes (isotopes having essentially infinite half-lives). The abundance of these isotopes is the same today as they were at the origin of the universe. Neither the patent issued to Welle nor Applicant's invention utilizes radioactive isotopes. Practically speaking, many of the radioactive isotopes cannot be used for product identification as these isotopes degrade over time and are not in the same concentration today as they are tomorrow.

The patent issued to Welle and Applicant's invention are representative of the two well defined and different ways of retrospectively identifying products utilizing stable, non-radioactive isotopes, i.e., respectively, "tagging" and "natural tracer" or "fingerprinting." The patent issued to Welle discloses a "tagging" method. Applicant claims a "natural tracer" method. The patent issued to Welle teaches a method by which an artificial taggant composition is inserted into a product such that it can be retrospectively identified. The taggant composition includes multiple stable isotopes in both abundance and kind typically not naturally found in the product. The measurement of these isotopes is utilized to retroactively identify that product at a

later time.

Tagging methods cannot be utilized in a number of instances. First, they cannot be used with previously-produced products that had no taggant material inserted into the product such as products manufactured before these methods were known and manufactured, and products in which taggant compositions are too expensive for use in identifying the product. Second, they cannot be utilized in products in which the purity or the toxicity of the product needs to be maintained such as with food and pharmaceuticals. These products include food products, pharmaceuticals, and all other products in which varying the composition would render the composition less desirable, toxic or useless. This point of "adding nothing" (including impurities) is central to Applicant's approach which is mainly focused on tracing the authenticity of pharmaceuticals. Whereas the US FDA is sharply critical of "added or spiked materials" which can bear upon the efficacy or safety of pharmaceuticals, the use of natural isotopes in natural or ambient concentrations provides no such problem or limitation as described in the "Natural Labelling" section (3.3) of the FDA/MIT LLC co-authored paper (Jasper et al., 2004, J. Pharm. Biomed Anal. 35(1):21-30) because "Natural labeling of products should presently be unaffected by regulatory authorities because this process simply takes advantage of natural isotopic variations which are implicitly already acceptable."

Applicant's method, using only naturally occurring stable isotopes, has the advantage over all methods utilizing a taggant composition such as disclosed by Welle, inasmuch as most taggant compositions are relatively expensive and the user of Applicant's method can ensure all that the initial purity of the product is maintained and that the product manufactured has not been altered.

Additionally, Applicant's method retrospectively identifies a product by comparing the

product's own molecular structure not something artificially added. In addition, the method of Welle retrospectively identifies the product by comparing additives to the product which typically are not molecularly bound to the product by chemical bonding, and thus, are loosely held in the product as a physical mixture or as a solution. All methods using taggant compositions including the method of the patent issued to Welle retrospectively identify products that, by analogy, are like comparing steaks by analyzing the additionally-added salt sprinkled on the steaks. In contrast, Applicant's method retrospectively identifies products by comparing with known reference standards the molecular structure of the product itself, i.e., the actual molecular structure of the protein of the steak. Thus, in utilizing Applicant's method, additional assurances against unwanted interferences, e.g., contamination by impurities, with the identification can be given to the user of Applicant's method.

Most of the prior art discloses tagging methods as much of the prior art has been developed in the field of geological exploration, prospecting in the petroleum industry, and medical studies in the health care industry. Tagging methods have been utilized to trace crude oil migration from one field to another. In addition, tagging methods have also been used in the medical field in performing tracer studies such as drug metabolism and biomedical studies. None of this prior art teaches or suggests the retrospective identification of products by Applicant's method.

Similarly, none of the prior art using taggant compositions such as disclosed by Welle teaches or suggests Applicant's method. Rather, Welle's art teaches away from using naturally occurring stable isotopes in retrospective identification of naturally occurring materials and materials produced by continuous processes, because crude oil from the same oil field but different spaced apart wells and oil refinery product of different calendar months have different

amounts of naturally occurring stable isotopes due to the wide range of natural organic materials forming the crude oil. As an example, batches of clam shells gathered off the coast of Ireland and clam shells gathered off the coast of Connecticut cannot be retrospectively distinguished by naturally occurring stable isotopes because of the natural variation or lack of homogeneity of the two groups of clams shells. Tagging methods such as disclosed by Welle were developed as means of tracing large doses of artificially-added (exogenous) isotopic tracers which overwhelmed and masked the naturally occurring isotopic variations of the material, should those exotic isotopes be present at all in the product of interest.

Applicant has been the first to devise a method by which naturally occurring stable isotopes in their naturally occurring or unaltered or ambient concentrations can be utilized to retrospectively identify products, trace these products through the manufacturing process, in the marketplace, and through various usages including potentially criminal or terrorist misusages of products or counterfeit products. Applicant's method applies only to batched products such as active pharmaceutical ingredients (API's), excipients of drug products, impurities in drug products, and other batched products. Naturally occurring products or products manufactured continuously cannot usually be retrospectively identified by Applicant's method as these products vary in time or location, depending upon formation process controls and raw materials, outside the scope of acceptable error. Both naturally occurring products and continuously manufactured products can be retrospectively identified by Applicant's method if those products are subsequently batched and the retrospective identification is between subsequently batched products. Applicant has provided a method by which naturally occurring stable isotopes may be used to retrospectively identify all batched products as long as they are initially or subsequently batched so as to be homogeneous within the error of the measurements.

Applicant's method is clearly usable to trace raw materials, ingredients, or synthetic intermediates through the manufacturing process, through the marketplace, and through the usage of all batch manufactured products, including pharmaceutical ingredients (API's), excipients of drug products, impurities of drug products, raw materials and synthetic intermediates in drug products, and other batched products and between such products and their counterfeit products. Applicant's method can be used to retrospectively identify products which are batch manufactured, such as the pharmaceutical products above mentioned to distinguish those products from counterfeit products, to distinguish the same products manufactured by different manufacturers, to distinguish the same products manufactured from different raw materials and synthetic intermediates, and to distinguish the same products manufactured in different batches.

Applicant's method was sought by the Federal Bureau of Investigation in determining the origin of anthrax powder sent to U.S. Senators' Office Building following the events of September 11, 2001. It has also been employed for tracing illicit . Applicant's method is also being seriously considered by international arson investigators and by the FBI in arson investigations to link accelerants found at fire scenes with batches of accelerants found on arson suspects or in suspected accelerant containers (see Jasper et al. (2002) Putting the arsonist at the scene: "DNA" for the fire investigator? Gas chromatography/isotope ratio mass spectrometry. *Fire Arson Investig.* 51(2): 30-34). Even though these arson accelerant materials are continuously manufactured at the refinery and the raw materials and the processing conditions at the refinery constantly change the isotopic concentrations, these materials are subsequently batched by mixing in small vessels such as accelerant containers such that Applicant's method utilizing naturally occurring stable isotopes can be used to link such evidentiary materials found

at the scene retrospectively to an accelerant container.

Similarly, with regard to naturally occurring materials, such as clam shells on two different shorelines, the prior art would indicate that analysis of naturally occurring stable isotopes would not within the error desired allow Applicant's method to distinguish clams from one shoreline from clams from another shoreline. However, if the clam shells on the two different shorelines were batched (sampled, pulverized to a microscopic scale, and mixed to be isotopically homogenous) identification of an unknown batch of clam shells could be linked to any one of the batches of clam shells by Applicant's method, but only to the shoreline if the sampling error was smaller than combined errors of batching and analysis.

So, much depends upon the error of sampling and the precision desired in the identification, that Applicant's method was not discovered until useful quantitative estimates of precision for molecular isotopic measurements were devised. See "Quantitative Estimates of Precision for Molecular Isotopic Measurements" Jasper, J.P. Rapid Communications in Mass Spectrometry, 2001, 15, 1554-1557. Now, because known elements have a total of 224 naturally occurring stable isotopes, the error of using Applicant's method in comparing two batched products can be reduced to exceptionally low levels by a standardized method. For example, using just the 13 different naturally occurring stable isotopes in the common light elements of carbon, hydrogen, oxygen, nitrogen, and sulfur, specificities can be achieved which, in the analysis and retrospective identification of products with their sources, would be greater than the precision achieved by DNA analysis (approximately 1 in 10 billion specificity). The specificity of the Applicant's method is proportional to the isotopic variation in a batched product induced by (i) the natural isotopic variations in its raw materials (thermodynamic variations), (ii) the anthropogenically-induced synthetic isotope variations (kinetic fractionations) and in the

precision of the requisite isotopic measurements. No analysis of such accuracy is either intended nor could it plausibly be obtained with taggant materials and the Welle method.

The patent issued to Welle (i) does not disclose or teach a method for identifying products limited to batched products, (ii) does not teach or suggest any method of identifying batched products utilizing naturally occurring stable isotopes in their naturally occurring concentrations, and (iii) does not teach or suggest any method of identifying batched products utilizing a mathematical or numerical array of concentrations from the analysis of naturally occurring stable isotopes as required by Applicant's method. The maximum number of isotopes disclosed by Welle is six, which is disclosed to produce one million unique codes at one percent precision. Applicant's method allows for the measurement of any of the naturally occurring stable isotopes of which there are a total of 224. Therefore, Applicant's method can be far more precise. For example, in typical pharmaceutical application, if one measures four isotope ratios each with a dynamic range of 1:100, one can be compounding those individual ranges to arrive at a predictable, estimated upper limit of probability of $1:100^4$, or 1:100,000,000. See the discussion of error in Applicant's Specification on pages 22-19.

Whenever a taggant composition is used, the taggant composition is added to the product being tested. The taggant is usually intermixed with the product, and thus, is loosely associated with the batch to be tested in a mixture or a solution rather than being chemically bonded to the product being compared. In contrast, Applicant utilizes naturally occurring stable isotopes within the matrix of the product itself. Welle does not teach any mathematical or numerical array of the isotopic concentrations of the product material itself. Welle only compares the isotopic concentration ratios of specific isotopes of the taggant material mixed in with the product.

The patent issued to Brand et al does not materially add to the disclosure of the patent issued to Welle. The patent issued to Brand et al produces concentrations which are readable, but not machine readable. The patent issued to Brand et al also only discloses a process for the analysis of gaseous components by mass spectrometry.

Applicant has recently received many unsolicited congratulatory comments regarding his "claimed identification" and methods. Applicant just returned from presenting his paper entitled "Multi Stable Isotopic Tracing of Pharmaceutical Identity" at the recent American Chemical Society "Pharmaceutical Authentication and Forensic Analysis" meeting and the Connecticut Separation Science Council meetings in May of 2004. These include: "Your presentation was excellent." Mohab M. Nasser, Ph.D., Director, Office of New Drug Chemistry, FDA. "The meeting and your presentation were brilliant, just brilliant." Dr. Susan Hilton, Senior Director of the Weinburg Group, Inc. "Trust me on this ... your excellent work will pay off." Dr. Amin Kamel (leading LC mass spectrometer senior research scientist at Pfizer Central Research, Groton, Connecticut) "The pharmaceutical isotope project is nice work and demonstrates a new and valuable approach for dealing with counterfeiting." Dr. Larry Weiner, Senior Research Fellow, Johnson & Johnson.

Thus, neither the patent issued to Welle, nor the patent issued to Welle in view of Brand et al teaches or suggests or renders obvious a method utilizing a batched product for the concentration of a plurality of naturally occurring isotopes of at least one of the elements of at least one of the compounds of said product, arranging the concentrations of the isotopes into a mathematical array, formulating the mathematical array into a readable form, or assembling the product information, indexing the product information in said readable form in an index, and maintaining the index and the product information as required by Claim 17 and Applicant's

method.

The patent issued to Welle and the patent issued to Welle in view of Brand et al do not teach or suggest or render obvious an identification for a composition comprising an arrangement of empirical information derived from the analysis of a plurality of naturally occurring stable isotopes of at least one of the chemical elements of the composition, the arrangement comprising a numerical array of said imperical information in a readable form as required by Applicant's Claim 42 and method.

The patent issued to Welle and the patent issued to Welle in view of Brand et al do not teach or suggest or render obvious the method of analyzing a plurality of naturally occurring stable isotopes of a composition, deriving empirical information from said analyzing step, and arranging said empirical information into a numerical array as required by Applicant's Claim 45.

The patent issue to Welle and the patent issued to Welle in view of Brand et al do not teach or suggest or render obvious the identifying of a plurality of the naturally occurring stable isotopes of a composition analyzing the composition for the concentrations of a plurality of naturally occurring stable isotopes of the composition deriving empirical information from said analyzing step, and arranging empirical information into a numerical array as required by Applicant's Claim 50.

The patents issued to Welle and Welle in view of Brand et al do not teach or suggest or render obvious the providing of an objective identification for a batched product comprising the steps of analyzing a batched product for the concentration of a plurality of naturally occurring stable isotopes of the product, arranging the concentrations of said isotopes into a mathematical array, formulating the mathematical array into a readable form, assembling product information with regard to said batched product, indexing said product information in said readable form to a

description of said product thereby forming an index, and maintaining said index and said product information and said readable form as required by Claim 70.

The patents issued to Welle and Welle in view of Brand et al do not teach or suggest or render obvious the identification for a batched product comprising an arrangement of empirical information derived from an analysis of a plurality of naturally occurring stable isotopes of said batched product, said arrangement comprising a numerical array of said empirical information in a readable form as required by Claim 71, or an identification for a batched product comprising empirical information derived from analysis of a plurality of naturally occurring stable isotopes of a batched product, said empirical information being arranged in a numerical array, said numerical array being in a readable form, said readable form being comparable to the empirical information of said naturally occurring isotopes of unknown products whereby unknown products can be identified with and differentiated from known products as required by Claim 72.

The patents issued to Welle and Welle in view of Brand et al do not teach or suggest or render obvious the linking of an unknown composition to known compositions comprising the steps of analyzing a plurality of stable naturally occurring isotopes of a plurality of known compositions, deriving empirical information from said analyzing step of said known compositions, arranging said empirical information from said known compositions into numerical arrays, indexing said numerical arrays of said known compositions in a readable form to product information of said known compositions, analyzing a plurality of stable naturally occurring isotopes of an unknown composition, deriving empirical information from said analyzing step performed on said unknown composition, arranging said empirical information from said unknown composition into a numerical array, comparing said numerical array of said unknown composition to said numerical arrays of said index, determining whether said

numerical array of said unknown composition matches any of the numerical arrays of said index as required by Claim 73

The patents issued to Welle and Welle in view of Brand et al do not teach or suggest or render obvious the linking of an unknown composition to known compositions comprising the steps of analyzing a first plurality of stable naturally occurring isotopes of a second plurality of elements of a third plurality of batched products thereby generating a fourth plurality of isotopic data, listing said fourth plurality of isotopic data, listing identifications of said third plurality of batched products and linking said identifications with said isotopic data thereby forming an index, analyzing a fifth plurality of stable naturally occurring isotopes of a sixth plurality of elements of an unknown batched product thereby generating a seventh plurality of isotopic data, comparing said seventh plurality of isotopic data with said fourth plurality of isotopic data to identify said unknown product as one of said third plurality of batched products or to distinguish said unknown product from said third plurality of batched products, said fifth, sixth, and seventh plurality being less or equal in number to said first, second, and fourth plurality, respectively, and determining the precision of said comparing step by selecting said fifth plurality of stable naturally occurring isotopes of said unknown product as required by Claim 74.

Claims 18, 20, 21, 41, 49, 53, 54, and 84 are each dependent upon Claim 17, thus each of these claims include all of the limitations of Claim 17 and are submitted to be patentable for the same reasons as reiterated above with regard to Claim 17. Claim 18 further requires:

> "the step of measuring the concentration of one or more of said isotopes in a comparable substance and comparing the concentration of said one or more isotopes of said comparable substance with the concentrations of said mathematical array in readable form to identify said substance."

Claim 20 further requires:

"said concentrations of isotopes are chosen from the group of isotopic concentrations consisting of concentrations of isotopes, concentrations of isotopes and their errors, and ratios of isotope concentrations, ratios of isotope concentrations and their errors and combinations thereof."

Claim 21 further requires:

"said readable form is a machine readable form of said mathematical array, said product information is placed on a machine, said machine readable form being indexed to said product information."

Claim 41 further requires:

"said mathematical array is chosen from the group of mathematical arrays consisting of a list of a plurality of concentrations, a list of a plurality of isotopic ratios, a list of a plurality of mathematical products of isotopic concentrations, a list of a plurality of mathematical products of isotopic ratios, groups of any such lists, groups of any such mathematical products, groups of any such ratios, groups of any such concentrations, mathematical products of any such concentrations plus or minus their error added, mathematical products of any such ratios plus or minus their error added, any such concentrations, ratios, lists, groups, and mathematical products in quadrature, isotopic ratios of any such mathematical products, ratios of said concentrations plus or minus their errors added, any of such concentrations plus or minus their errors added, factor analysis of any such concentrations, ratios, lists, groups, mathematical products and any determinants and combinations thereof."

Claim 49 further requires:

"the step of increasing the composition of at least one of the plurality of naturally occurring stable isotopes of said composition, and analyzing the same as part of said analyzing step."

Claim 53 further requires:

"said readable form is chosen from the group of readable forms consisting of serial numbers, bar codes, and other numerical and alphabetical indicia."

Claim 54 further requires:

> "the isotopes available are any of the 224 existing stable isotopes of known elements which have two or more isotopes."

Claim 84 further requires:

> "said analyses of said analyzing steps each have a dynamic range equal to the observed range divided by the 1-sigma standard deviation."

Claims 22 and 24 are dependent upon Claims 21 and 17, thus Claims 22 and 24 include all of the limitations of Claims 21 and 17 and are submitted to be patentable for the same reasons as reiterated above with regard to Claims 21 and 17. Claim 22 further requires:

> "said product information may be displayed by identifying said machine readable form and indexing the same to said product information."

Claim 24 further requires:

> "measuring the concentration of said isotopes in a comparable substance, arranging said comparable substance concentrations into a mathematical array, and comparing the mathematical array of said comparable substance with said mathematical array of said product."

Claim 23 is dependent upon Claims 22, 21, and 17, thus Claim 23 includes all of the limitations of Claims 22, 21, and 17 and is submitted to be patentable for the same reasons as reiterated above with regard to Claims 22, 21, and 17. Claim 23 further requires:

> "said product information may be scrolled and/or downloaded or printed as desired."

Claims 25-33, 36 and 37 are each dependent upon Claims 24, 21, and 17, thus Claims 25-33, 36 and 37 each include all of the limitations of Claims 24, 21 and 17 and are submitted to be patentable for the same reasons as reiterated above with regard to Claims 24, 21, and 17. Claim 25 further requires:

> "said mathematical array includes ratios, concentrations, and products and said comparing step comprises comparing each of

said ratios, concentrations or products step by step to identify said comparable substance within the error desired."

Claim 26 further requires:

"said concentrations of isotopes are chosen from the group of isotopic concentrations consisting of concentrations of isotopes, concentrations of isotopes and their errors, and ratios of isotope concentrations, ratios of isotope concentrations and their errors."

Claim 27 further requires:

"said readable form is chosen from the group of readable forms consisting of serial numbers, bar codes, and other numerical and alphabetical indicia."

Claim 28 further requires:

"said mathematical array is chosen from the group of mathematical arrays consisting of a list of a plurality of concentrations, a list of a plurality of isotopic ratios, a list of a plurality of mathematical products of isotopic concentrations, a list of a plurality of mathematical products of isotopic ratios, groups of any such lists, groups of any such mathematical products, groups of any such ratios, groups of any such concentrations, mathematical products of any such concentrations plus or minus their error added, mathematical products of any such ratios plus or minus their error added, any such concentrations, ratios, lists, groups, and mathematical products in quadrature, isotopic ratios of any such mathematical products, ratios of said concentrations plus or minus their errors added, any of such concentrations plus or minus their errors added, factor analysis of any such concentrations, ratios, lists, groups, mathematical products and any determinants and combinations thereof."

Claim 29 further requires:

"the isotopes available are any of the 224 existing stable isotopes of known elements which have two or more isotopes."

Claim 30 further requires:

"said isotopes are of any of the 13 stable isotopes of the group of elements consisting of carbon, hydrogen, oxygen, nitrogen, sulfur and combinations thereof."

Claim 31 further requires:

> "the error of identification is chosen by the mathematical array chosen, the number of concentrations of isotopes utilized in said array, and the portion of said array compared with the isotopic analysis of said unknown product."

Claim 32 further requires:

> "the batched product from which the concentrations of isotopes are analyzed and formed into a mathematical array is chosen from the group of batched products consisting of active pharmaceutical ingredients, excipients of drug products, impurities in drug products, raw materials and drug products, combustible fuels, additives to combustible fuels, environmental and natural occurring products, explosives and ammunition, gun powder, crude oil, petroleum distillates, hazardous waste, paper, ink, tire materials, paints and other coatings, and other synthetic materials."

Claim 33 further requires:

> "said concentrations of isotopes are chosen from the group of concentrations of isotopes consisting of bulk phase analysis and specific compound analysis."

Claim 36 further requires:

> "said analyses include nuclear magnetic resonance."

Claim 37 further requires:

> "said readable form is a machine readable form and said product information is stored in memory on a machine together with the index, said machine readable form, index and product information being interlinked, said machine readable form once identified through the index presents stored product information in displayed form."

Claims 34 and 35 are each dependent upon Claims 33, 24, 21, and 17, thus Claims 34 and 35 each include all of the limitations of Claims 33, 24, 21, and 17 and are submitted to be patentable for the same reasons as reiterated above with regard to Claims 33, 24, 21, and 17.

Claim 34 further requires:

"said bulk phase analysis includes off-line dual inlet isotope ratio mass spectrometry and on-line combustion coupled with high resolution isotope ratio monitoring/mass spectrometry."

Claim 35 further requires:

"specific compound analysis includes gas chromatography coupled with irMS and liquid chromatography coupled with irMS."

Claims 38-40 are each dependent upon Claims 37, 24, 21, and 17, thus Claims 38-40 each include all of the limitations of Claims 37, 24, 21, and 17 and are submitted to be patentable for the same reasons as reiterated above with regard to Claim 17. Claim 38 further requires:

"said product information may be scrolled through."

Claim 39 further requires:

"said product information may be printed."

Claim 40 further requires:

"said product information may be accessed through said index from said machine readable form of said mathematical array."

Claims 43, 44, 55-59, 61, 65, and 66 are each dependent upon Claim 42, thus Claims 43, 44, 55-62, 65 and 66 each include all of the limitations of Claim 42 and are submitted to be patentable for the same reasons as reiterated above with regard to Claim 42. Claim 43 further requires:

"said empirical information further comprises the tolerable error of said analysis."

Claim 44 further requires:

"said composition is a substance manufactured in an industry chosen from the group of industries consisting of the chemical, petroleum, pharmaceutical, biomedical, biochemical, environmental, paint, explosive material and combustible fuel industries."

Claim 55 further requires:

"said empirical information is chosen from the group of empirical information consisting of concentrations of isotopes, concentrations of isotopes and their errors, ratios of isotope concentrations, ratios of isotope concentrations and their errors and combinations thereof."

Claim 56 further requires:

"said readable form is chosen from the group of readable forms consisting of serial numbers, bar codes, and other numerical and alphabetical indicia."

Claim 57 further requires:

"said mathematical array is chosen from the group of mathematical arrays consisting of a list of a plurality of concentrations, a list of a plurality of isotopic ratios, a list of a plurality of mathematical products of isotopic concentrations, a list of a plurality of mathematical products of isotopic ratios, groups of any such lists, groups of any such mathematical products, groups of any such ratios, groups of any such concentrations, mathematical products of any such concentrations plus or minus their error added, mathematical products of any such ratios plus or minus their error added, any such concentrations, ratios, lists, groups, and mathematical products in quadrature, isotopic ratios of any such mathematical products, ratios of said concentrations plus or minus their errors added, any of such concentrations plus or minus their errors added, factor analysis of any such concentrations, ratios, lists, groups, mathematical products and any determinants and combinations thereof."

Claim 58 further requires:

"said isotopes are any of the 224 existing stable isotopes of known elements which have two or more isotopes."

Claim 59 further requires:

"said isotopes are of any of the 13 stable isotopes of the group of elements consisting of carbon, hydrogen, oxygen, nitrogen, sulfur and combinations thereof."

Claim 61 further requires:

"the batched product from which the concentrations of isotopes are analyzed and formed into a mathematical array is chosen from the

group of batched products consisting of active pharmaceutical ingredients, excipients of drug products, impurities in drug products, raw materials and drug products, combustible fuels, additives to combustible fuels, environmental, natural occurring products, explosives products, ammunition, gun powder, crude oil, petroleum distillates, hazardous waste, paper, ink, tire materials, paints and other coatings, and other synthetic materials."

Claim 65 further requires:

"said analyses include nuclear magnetic resonance."

Claim 66 further requires:

"said readable form is a machine readable form that is comparable to other machine readable forms derived from the analysis of known products and their product information stored in memory on a machine together with an index, said machine readable forms, index, and product information being interlinked, said machine readable forms once identified through the index presents stored product information in displayed form."

Claim 46 is dependent upon Claim 45, thus Claim 46 includes all of the limitations of Claim 45 and is submitted to be patentable for the same reasons as reiterated above with regard to Claim 45. Claim 46 further requires:

"said analyzing step comprises determining ratios of measured concentrations of two or more stable isotopes of said composition."

Claim 47 is dependent upon Claims 46 and 45, thus Claim 47 includes all of the limitations of Claims 46 and 45 and is submitted to be patentable for the same reasons as reiterated above with regard to Claims 46 and 45. Claim 47 further requires:

"the steps of performing the method of Claim 46 for a plurality of known compositions, indexing said numerical arrays for said known compositions in a readable form into an index linking said numerical arrays to product information for a plurality of known compositions, performing the method of Claim 46 for said unknown composition, comparing said numerical array for said unknown composition to said numerical arrays of said index, determining whether said numerical array for said unknown composition matches any of the numerical arrays contained in said

> index, and matching said numerical array of said unknown composition to the numerical array of a known composition in said index thereby identifying said unknown composition or distinguishing said unknown composition from said known compositions of said index."

Claims 63 and 64 are each dependent upon Claims 62 and 42, thus Claims 63 and 64 each include all of the limitations of Claims 62 and 42 and are submitted to be patentable for the same reasons as reiterated above with regard to Claims 62 and 42. Claim 63 further requires:

> "said bulk phase analysis includes off-line dual inlet isotope ratio mass spectrometry (irMS) and on-line combustion coupled with high resolution isotope ratio monitoring/mass spectrometry (irmMS)."

Claim 64 further requires:

> "specific compound analysis includes gas chromatography coupled with irMS (irmGCMS) and liquid chromatography coupled with irMS (irmLCMS)."

Claims 67-69 are each dependent upon Claim 42, thus Claims 67-69 each include all of the limitations of Claim 42 and are submitted to be patentable for the same reasons as reiterated above with regard to Claim 42. Claim 67 further requires:

> "said product information may be scrolled through."

Claim 68 further requires:

> "said product information may be printed."

Claim 69 further requires:

> "said product information may be accessed through said index from said machine readable form of said mathematical array."

Claims 75-78, 81-83, and 86-89 are each dependent upon Claim 74, thus, Claims 75-78, 81-83, and 86-89 each include all of the limitations of Claim 74 and are submitted to be allowable for the same reasons as reiterated above with regard to Claim 74. Claim 75 further

requires:

> "said analyzing said first plurality and fifth plurality include analyses chosen from the group of analyses consisting of bulk phase analyses including offline dual inlet isotope radio mass spectrometry (IRMS) and online combustion coupled with high resolution isotope ratio monitoring/mass spectrometry (IRMS), NMR, and specific compound analyses including gas chromatography coupled with IRMS (IRMGCMS) and liquid chromatography coupled with IRMS (IRMLCMS)."

Claim 76 further requires:

> "said stable naturally occurring isotopes include any of the 224 existing stable isotopes of known elements that have two or more isotopes."

Claim 77 further requires:

> "said stable naturally occurring isotopes are any of the 13 stable isotopes of the group of elements consisting of carbon, hydrogen, oxygen, nitrogen, sulfur and combinations thereof."

Claim 78 further requires:

> "said fourth plurality of isotopic data are arranged in a plurality of mathematical arrays being presented in a readable form."

Claim 81 further requires:

> "said identification listing results in a list of physical properties of said third plurality of batched products."

Claim 82 further requires:

> "said identification listing results in a list of chemical properties of said third plurality of batched products."

Claim 83 further requires:

> "said unknown batched product is a sample of a product larger in volume of said sample, and said sampling of said larger in volume products is more precise than the precision of said comparing step."

Claim 86 further requires:

"the specificity of said comparing step using analyses of C^{13}, N^{15}, O^{18} and H^3 is determined by the following equations of the form: Specificity = $(1\sigma-\delta^{13}C/\Delta\delta^{13}C)*(1\sigma-\delta^{15}N/\Delta\delta^{15}N)*(1\sigma-\delta^{18}O/\Delta\delta^{18}O)*(1\sigma-\delta D/\Delta\delta D)$."

Claim 87 further requires:

"the specificity of said comparing step is inversely proportional to the product of the dynamic ranges of each isotopic analysis undertaken of said unknown batched product."

Claim 88 further requires:

"the precision of said comparing step is increased by compounding the precisions of said seventh plurality of isotopic data."

Claim 89 further requires:

"the predicted degree of specificity of said comparing step is inversely proportional to the product of the dynamic ranges for each isotopic analyses undertaken in analyzing said fifth plurality of stable naturally occurring isotopes of a sixth plurality of elements of said unknown product."

Claims 79 and 80 are each dependent upon Claims 78 and 74, thus Claims 79 and 80 each include all of the limitations of Claims 78 and 74 and are submitted to be allowable for the same reasons as reiterated above with regard to Claims 78 and 74. Claim 79 further requires:

"said readable form is chosen from the group of readable forms consisting of serial numbers, bar codes and other numerical and alphabetical indicia."

Claim 80 further requires:

"said fourth plurality listing step results in a list of machine readable arrays."

Claim 85 and 90 are each dependent upon Claims 84 and 17, thus Claims 85 and 90 each include all of the limitations of Claims 84 and 17 and are submitted to be allowable for the same reasons as reiterated above with regard to Claims 78 and 17. Claim 85 further requires:

"the precision of each of said analyses is the 1-sigma standard

deviation of the analysis preformed divided by the square root of the number of observations of said analysis."

Claim 90 further requires:

"the dynamic range is the range of values expected for an analysis divided by the 1-sigma standard deviation of that analysis."

The amendments made herein merely adopt the Examiner's suggestions, remove issues for appeal and requires only a cursory review by the Examiner. This amendment places all of the claims pending in form for immediate allowance. No new matter has been added; no new issues have been raised.

For all of the reasons above given Applicant respectfully submits that each of the claims of the application, as amended, patentably distinguish Applicant's invention from the patents cited and/or applied by the Examiner, whether taken alone or in combination with each other. Applicant respectfully solicits a prompt issuance of a Notice of Allowance.

Respectfully submitted,

David A. Lundy
Reg. No. 22,162

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